UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MASSACHUSETTS

IN RE PHARMACEUTICAL INDUSTRY AVERAGE WHOLESALE PRICE LITIGATION	))))
	MDL No. 1456
	CIVIL ACTION: 01-CV-12257-PBS
THIS DOCUMENT RELATES TO 01-CV-12257-PBS AND 01-CV-339	)))))
	Judge Patti B. Saris
	Chief Magistrate Judge Marianne B. Bowler
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	[FILED UNDER SEAL PURSUANT TO COURT ORDER]

DECLARATION OF RAYMOND S. HARTMAN IN SUPPORT OF PLAINTIFFS' MOTION FOR CLASS CERTIFICATION

Declaration of Raymond S. Hartman
In Support of Certification of Class

In the Matter of the Pharmaceutical Industry
Average Wholesale Price Litigation

Executive Summary

I have analyzed whether the members of each of the End-Payer Classes identified in the Plaintiffs' Motion for Class Certification have been injured and damaged as a Class as a result of the alleged AWP scheme. I conclude that they were for the following reasons. First, the AWP (average wholesale price) is the industry benchmark for reimbursement for drugs administered under Medicare Part B and for all other drugs reimbursed subject to contracts and/or pricing formulae using AWP. AWP is interpreted by the industry as a measure of the underlying structure of drug prices. Second, assuming the allegations are true, Defendant Drug Manufacturers offered discounts, rebates and/or other price offsets to specifically targeted entities (providers, PBMs and retailers) that had the ability to "move market share." These price offsets reduced the actual transaction price at which the drugs were sold by manufacturers. Given the lack of pricing transparency in this industry, these reductions in transaction prices were not apparent to the members of the End-Payer Classes, and the AWPs were therefore overstated and inflated relative to the prices at which manufacturers sold the relevant drugs. This inflation is the basis for causation, injury and damages on a class-wide basis.

The extent to which the AWP scheme caused injury and damages was determined by the extent to which the AWP was inflated. The extent to which the AWP was inflated in turn increased the incentives to those entities moving market share.

I have analyzed whether there exist standard formulaic methodologies to demonstrate the existence of and measure the extent of class-wide injury and damages. I conclude and demonstrate that such formulaic methodologies do exist; the methodologies make use of standard economic analysis. I demonstrate that the measure of damages is directly related to the extent to which the AWP was inflated above the "but-for" AWP, that is, the AWP that would have been reported absent the AWP scheme. Since reimbursement rates paid by Class members were directly and formulaically related to AWP, those reimbursement rates were inflated to the extent that the AWP was inflated. I demonstrate that market participants reasonably expected that the "but-for" AWP was related to a drug's average sale price (ASP). Using that expectation, I can calculate the AWP inflation caused by the AWP scheme for each drug affected and the resulting aggregate overcharges in reimbursements paid by the Classes. I also demonstrate how the formulaic methodologies can be used to calculate damages for particular sub-groups of Class members.

This Declaration proceeds as follows. In Section I, I present my qualifications. In Section II, I review the allegations and conclude that, if proven true, the various Classes suffered class-wide injury and were damaged economically in the form of overcharges for drug reimbursements. In Section III, I present an analysis of the pharmaceutical industry supporting this conclusion, drawing from Attachments C through

IV.   Formulaic Methods for Analyzing the Class-Wide Injury Caused by the AWP Scheme

A.   General Formulation.

20.   To the extent that the alleged AWP scheme was effectuated by Defendants, they would reveal themselves in "excessively" large spreads or deviations between the inflated AWP and the transaction price (ASP) for which the AWP is taken as a signal. These spreads can be measured as (AWP – ASP), (AWP/ASP), (AWP – ASP)/AWP or (AWP – ASP)/ASP;[40]   the precise measure used will depend upon the analytic needs of the formulaic models.

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[40] Note that in the last two forms, the measure of spread resembles the Lerner Index, a standard economic measure of revealed market power.

In order to evaluate whether spreads for particular drugs were excessively large, one must first calculate the actual spreads for the drugs allegedly subject to the AWP scheme and, second, compare those spreads to "but-for spreads," that is, spreads whose AWP and ASP are unaffected by the AWP scheme and fraud. If the actual spread exceeds the but-for spread, I can conclude that the AWP scheme led to reimbursement in excess of those reasonably expected by the market.

21.   More specifically, the actual spread for any drug can be calculated using data on its AWP from one or several of the accepted industry price compendia and data on its ASP derived from detailed analysis of Defendant Drug Manufacturers' invoice and accounting data. Denote that actual spread for drug j of Defendant k as $Spread_{jk}$, for any Defendant k and any named drug j.

But-for spreads can be calculated using industry-wide survey information concerning expectations regarding the relationship between AWP and ASP for drugs unaffected by the AWP scheme and/or by using actual AWP and ASP data from those manufacturers and their drugs known to be unaffected by the AWP scheme. Denote such a but-for spread as $Spread_{jk}^{but\text{-}for}$. I discuss the foundation for and the calculation of $Spread_{jk}^{but\text{-}for}$ in ¶¶ 28-33 below.

Using this notation, the alleged AWP scheme excessively raised reimbursement rates for drug j of Defendant k if

(1a) $Spread_{jk} > Spread_{jk}^{but\text{-}for}$.

22.   Put alternatively, since the industry expects AWP to be a reasonable signal for ASP and vice versa, then the observed spread will suggest that AWP is unreasonably and fraudulently high when[41]

(1b) $Spread_{jk} = (AWP_{jk} - ASP_{jk})/ASP_{jk} > Spread_{jk}^{but\text{-}for} = (AWP_{jk}^{but\text{-}for} - ASP_{jk})/ASP_{jk}.$

The extent to which the measured $Spread_{jk}$ exceeds the $Spread_{jk}^{but\text{-}for}$ will determine the extent to which the actual AWP_{jk} exceeds the AWP that is reasonably expected given ASP, that is, the $AWP_{jk}^{but\text{-}for}$.

23.   For example, suppose $Spread_{jk}$ is 4 times larger than $Spread_{jk}^{but\text{-}for}$ and that $Spread_{jk}^{but\text{-}for}$ equals 25%.[42] Because $Spread_{jk}^{but\text{-}for} = 25\%$, $(AWP_{jk}^{but\text{-}for} - ASP_{jk})/ASP_{jk} = 0.25$ (25%), which implies that the but-for relationship between AWP and ASP is $AWP_{jk}^{but\text{-}for} = 1.25*ASP_{jk}$. This implies that when the industry observes AWP, it is reasonable to expect that the ASP is 80% below that AWP. Likewise, when a manufacturer has a given ASP, it is reasonable to expect that it will list its AWP at 1.25 times that ASP.

However, if $Spread_{jk} = 100\%$, then $(AWP_{jk} - ASP_{jk})/ASP_{jk} = 1.00$ (100%), which implies that $AWP_{jk} = 2.00*ASP_{jk}$. By implication,

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[41] Note that this derivation is based upon expressing the Spread as (AWP-ASP)/ASP. Had the Spread been expressed as (AWP-ASP) or as (AWP-ASP)/AWP, the calculations would have been appropriately altered.

[42] That is, $Spread_{jk} = 4*Spread_{jk}^{but\text{-}for} = 100\%$.

- The extent to which reimbursement rates have been characterized by several standard relationships to AWP (AWP − x%, x = several values) or rather best characterized by an average relationship to AWP.

- The extent to which the relationship between reimbursement rates and the AWP can be characterized by the type and size of the TPP and the related pharmacy benefit plan(s); by the type of drug; and by any other relevant factors.

I declare under penalty of perjury that this Declaration is true and correct. Executed on September 3, 2004.

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Raymond S. Hartman